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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,178	10/29/2003	Katerina Leftheris	QA0237 Div 1	6531

23914 7590 02/28/2006

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EXAMINER
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PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/696,178

Applicant(s)

LEFTHERIS ET AL.

Examiner

Alton N. Pryor

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/29/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing instant compounds for treating conditions associated with p38 kinase activity, does not reasonably provide enablement for using instant compounds for treating all conditions in claims 8-9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Many of these conditions are unrelated, e.g. asthma, pain, fever, edema, analgesia, viral disease, angiogenic disorder, autoimmune disease, bone disorder, infectious disease, inflammation (arthritis), diabetes, respiratory distress syndrome, pulmonary disease, atherosclerosis, or psoriasis. For this reason, one having ordinary skill in art would be required to do extensive experimentation to determine which condition would be treatable using instant compounds. The predictability in this art is high since the many of the diseases are unrelated and the mechanism of action of treating one condition may be totally different from the mechanism of action of treating an unrelated disease. Thus, one of ordinary skill in the art would not know based on the specification which compound would be effective at treating which condition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "NH-phenyl moiety" in line 3. There is insufficient antecedent basis for this limitation in the claim. Note that claim 4 states R4 and R5 taken together with Z to form said phenyl moiety. However, in the moiety Z = N; R5 = H; and R4 = substituted phenyl. Therefore, R4 and R5 cannot be taken together to form the NH-phenyl moiety.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (US 6982265; 1/3/06). Hunt teaches the pyrrolotriazine compound of Example 19 which is the compound in instant method claims where R1 = H; X = CO<sub>2</sub>; R2, R3 = Me; ZR5 = NH; R4 = substituted phenyl; R13 = alkyl; and R12 – OR14; R14 = H. See Example 19. Hunt teaches that pyrrolotriazine compounds of his invention can be used in methods of treating cancer, psoriasis, arthritis, inflammation, autoimmune disease, and diabetic retinopathy. See column 6 line – column 7 line 10. These are conditions associated with p38 kinase activity as indicated in instant claims 7-11. Hunt does not exemplify methods of treating said conditions with his compound shown in

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Example 19. However, it would have been obvious to one having ordinary skill in the art to have employed the compound of Example 19 in methods of treating said conditions. One would have been motivated to do this since Hunt states that his invention is based on the discovery that certain pyrrolotriazines are inhibitors of protein kinases. See column 6 lines 44-45. With respect to claims 5 and 6, Hunt suggests the method of using compounds where X-R2 = N-R10CO-alkyl; Y = absent; R3 = substituted alkyl; R5,R1 = H; R6 = H, alkyl; Z = N; R4 = sulfonamide substituted aryl. This compound is the instant compound where X-R2 = N-R10CO-alkyl (R2a,R10 = H); R3 = Me or trifluoromethyl; R1,R5 = H; R6 = H, alkyl; Y= SO2NH (sulfonamide). Hunt does not exemplify a method of treating said conditions using this compound. However, it would have been obvious to one having ordinary skill in the art to have employed the compound in methods of treating said conditions. One would have been motivated to do this since Hunt states that his invention is based on the discovery that certain pyrrolotriazines are inhibitors of protein kinases. See column 6 lines 44-45.

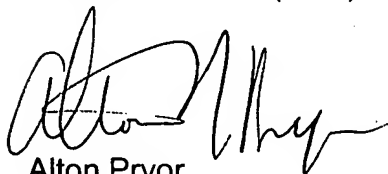
### ***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton Pryor', is written over the printed name.

Alton Pryor  
Primary Examiner  
AU 1616